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EXAMINER
EISENSCHENK, F

ART UNIT	PAPER NUMBER
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This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 5/13/96 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), — days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☒ Notice of References Cited by Examiner, PTO-892.
2. ☒ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☒ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____.

Part II SUMMARY OF ACTION

1. ☒ Claims 9-10 are pending in the application.

Of the above, claims _____ are withdrawn from consideration.

2. ☒ Claims 1-8, 11-27 have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 9-10 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

PTOL-326 (Rev. 2/93)

15. Applicant's election of claims 9-10 in Paper No. 10, filed 5/13/96 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (M.P.E.P. § 818.03(a)).

16. Applicant is reminded that the photographs are not acceptable until a petition is granted, see box 2 of the PTO 948 form, attached to Paper No. 4. Applicant is reminded that if color photographs are included in this application, the specification must be amended, at the first paragraph in the part of the specification relating to the brief description of the drawings, to include the following statement "[t]he file of this patent contains at least one drawing executed in color. Copies of this patent with color drawing(s) will be provided by the Patent and Trademark Office upon request and payment of the necessary fee."

17. Claims 9-10 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

    A) The claims are indefinite in that they depend upon a non-elected claim. It is suggested that the language of claim 3 be incorporated into the language of claim 9.

18. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:
A person shall be entitled to a patent unless --

    (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

19. Claims 9-10 are rejected under 35 U.S.C. § 102(b) as anticipated by, or in the alternative, 35 U.S.C. § 103 as obvious over McDonald et al. (Proc. Soc. Exper. Biol. Med.) as evidenced by Gurney et al. (Blood). The claims are drawn to monoclonal antibodies and hybridomas which produce said monoclonal antibodies which specifically bind to the mpl ligand. McDonald teach monoclonal antibodies and hybridomas producing the same which specifically bind to thrombopoietin. Thrombopoietin is art recognized to be the same protein as the mpl ligand (see Introduction, Gurney et al.)

    The instant claims, drawn to a monoclonal antibody and hybridoma which

specifically binds to the mpl ligand with a defined amino terminal sequence differ from the prior art monoclonal antibody and hybridoma, if at all, in the specific recitation of laboratory designations and other biological activities unrecited by the prior art. However, such characteristics are considered to be inherent for the prior art antibody which is otherwise the same as the present antibody. In addition, no showing or evidence is of record which verifiably establishes any non-obvious or unexpected differences between the prior art antibody and the instant antibody. Even if the prior art antibody is not identical to that instantly claimed, the information in McDOnald et al. specifically characterizing the monoclonal antibodies disclosed therein, in combination with conventional techniques for the production of monoclonal antibodies and hybridomas would have allowed the ordinary artisan to produce hybridomas and monoclonal antibodies of similar, if not identical, specificities with a reasonable expectation of success.

20. The office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. See Ex parte Phillips, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.).

21. The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

22. Claims 9-10 are rejected under 35 U.S.C. § 103 as being unpatentable over McDonald et al. (J. Lab. Clin. Med. or Exp. Hematol.) in view of Kohler et al. or Hammerling et al. (admitted prior art relating to the manufacture of monoclonal antibodies to antigens, page 56-60, specification). McDonald et al. both teach the purification and isolation of thrombopoietin. This protein has a Mr of about 32,000 and has biological properties similar to those of the mpl ligand against which the claimed antibodies and hybridoma were generated. The references do not teach hybridomas or monoclonal antibodies which specifically bind to the mpl ligand. Kohler et al. and Hammerling et al. both teach the production of monoclonal antibodies against a variety of antigens. Indeed, methods of making monoclonal antibodies and the hybridomas which produce said antibodies are well known in the art . One of ordinary skill in the art would have been motivated to make hybridomas and monoclonal antibodies to the mpl ligand in order to construct affinity chromatography columns for the purification of the ligand or to use the monoclonal antibodies as reagents for the detection of the mpl ligand in serum samples. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

23. 35 U.S.C. § 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claims 9-10 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 9-10 of copending application Serial No. 08/430,010, claims 20-21 of application 08/433,767, and claims 6-7 of copending application 08/429,765. Although the conflicting claims are not identical, they are not patentably distinct from each other because the recited claims of this invention are an species within the broader genus of the claims found in the '010 application. This is a *provisional* obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The obviousness-type double patenting rejection is a judicially established doctrine based upon public policy and is primarily intended to prevent prolongation of the patent term by prohibiting claims in a second patent not

patentably distinct from claims in a first patent. *In re Vogel*, 164 USPQ 619 (CCPA 1970). A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(b) would overcome an actual or provisional rejection on this ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. § 1.78(d).

Claims 9-10 are provisionally rejected under 35 U.S.C. § 101 as claiming the same invention as that of claims 13-14 of copending application Serial No. 08/422,548. This is a *provisional* double patenting rejection since the conflicting claims have not in fact been patented.

24. No claim is allowed.

25. Papers related to this application may be submitted to Group 180 by facsimile transmission. Papers should be faxed to Group 180 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-7401.

26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher Eisenschenk whose telephone number is (703) 308-0452. The examiner can normally be reached Monday through Thursday from 6:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. The fax phone number for Group 180 is (703) 305-3014 or (703) 305-7401. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 180 receptionist whose telephone number is (703) 308-0196.

C Eisenschenk

August 1, 1996
Christopher Eisenschenk, Ph.D.
Primary Examiner
Group 1800